Serial No.: 10/536950 Attorney Docket No.: DFMP-P01-480

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (currently amended) A composition useful for the prophylaxis and/or treatment of an individual afflicted with a Hepatitis C virus (HCV) infection and/or at least one disease associated with a HCV infection, said composition comprising at least one agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D_3, all trans retinoic acid, salts of all trans retinoic acid, C_1 - C_{10} alkyl esters of all trans retinoic acid, salts of C_1 - C_{10} alkyl esters of all trans retinoic acid, C_1 - C_{10} alkyl amides of all trans retinoic acid, salts of C_1 - C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C_1 - C_{10} alkyl esters of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl esters of 9-cis retinoic acid, C_1 - C_{10} alkyl amides of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2- naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-~~naphtalenyl~~ naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (~~4-~~HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN).

2. (original) The composition according to claim 1, wherein the composition comprises from 0.01 to 0.15 % by weight of the agent(s).

3. (currently amended) The composition according to claim ~~1 or~~ 2, wherein the composition comprises from 0.02 to 0.05 % by weight of the agent(s).

4. (currently amended) The composition according to ~~one of the preceding claims~~claim 1, wherein the selenium salt is sodium selenite.

5. (currently amended) The composition according to claim 1~~one of the preceding claims~~, wherein the composition further comprises at least one of the following compounds[,]: pegylated α-, β-, and/or γ-interferon, non-pegylated (standard) α-, β-, and/or γ-interferon, and ribavirin.

6. (currently amended) The composition according to claim 1~~one of the preceding claims~~, wherein the composition further comprises paraquat.

7. (currently amended) The composition according to claim 1~~one of the preceding claims~~, further comprising at least one pharmaceutically acceptable carrier, excipient and/or diluent.

8. (currently amended) The composition according to claim 1~~one of the preceding claims~~, wherein the individual afflicted with a HCV infection and/or at least one disease associated with HCV infection is a non-responder to interferon and/or ribavirin therapy.

9. (currently amended) A method for regulating the production of Hepatitis C virus in an individual and/or for preventing and/or treating Hepatitis C virus infection and/or diseases associated with HCV infection in an individual, the method comprising administering a pharmaceutical composition comprising a pharmaceutically effective amount of at least one agent selected from selenium, selenium salts, Vitamin D_3, all trans retinoic acid, C_1 - C_{10} alkyl esters of all trans retinoic acid, salts of C_1 - C_{10} alkyl esters of all trans retinoic acid, C_1 - C_{10} alkyl amides of all trans retinoic acid, salts of C_1 - C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C_1 - C_{10} alkyl esters of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl esters of 9-cis retinoic acid, C_1 - C_{10} alkyl amides of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl]benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)carboxamido]benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN) to the individual.~~Use of at least one~~

~~of the agents selenium, selenium salts, Vitamin D_3, all trans retinoic acid, C_1 – C_{10} alkyl esters of all trans retinoic acid, salts of C_1 – C_{10} alkyl esters of all trans retinoic acid, C_1 – C_{10} alkyl amides of all trans retinoic acid, salts of C_1 – C_{10} alkyl amides of all trans retinoic acid, 9 cis retinoic acid, salts of 9 cis retinoic acid, C_1 – C_{10} alkyl esters of 9 cis retinoic acid, salts of C_1 – C_{10} alkyl esters of 9 cis retinoic acid, C_1 – C_{10} alkyl amides of 9 cis retinoic acid, salts of C_1 – C_{10} alkyl amides of 9 cis retinoic acid, (E) 4 [2 (5,6,7,8 tetrahydro 5,5,8,8 tetramethyl 2 naphthalenyl 1 propenyl] benzoic acid (TTNPB), (4 [5,6,7,8 tetrahydro 5,5,8,8 tetramethyl 2 naphtalenyl) carboxamido] benzoic acid (AM 580), N (4 hydroxyphenyl) retinamide (4 HPR), and 6 [3 (1 adamantyl) 4 hydroxyphenyl] 2 naphthalene carboxylic acid (AHPN) for the preparation of a pharmaceutical composition for the treatment and/or prophylaxis of a Hepatitis C virus infection and/or a disease associated with HCV infection.~~

10. (currently amended) ~~Use~~ The method according to claim 9, wherein the pharmaceutical composition comprises from 0.01 to 0.15 % by weight of the agent(s).

11. (currently amended) The method ~~Use~~ according to claim ~~9 or~~ 10, wherein the pharmaceutical composition comprises from 0.02 to 0.05 % by weight of the agent(s).

12. (currently amended) The method ~~Use~~ according to ~~one of claims 9 to 11~~ claim 9, wherein the selenium salt is sodium selenite.

13. (currently amended) The method ~~Use~~ according to claim 9 ~~one of claims 9 to 12~~, wherein the pharmaceutical composition further comprises at least one of the following compounds[,]: pegylated α-, β-, and/or γ-interferon, non-pegylated (standard) α-, β-, and/or γ-interferon, and ribavirin.

14. (currently amended) The method ~~Use~~ according to claim 9 ~~one of claims 9 to 13~~, wherein the pharmaceutical composition further comprises paraquat.

15. (currently amended) The method ~~Use~~ according to ~~one of claims~~ claim 9 ~~to 14~~, wherein said pharmaceutical composition is for oral application.

16. (currently amended) The method ~~Use~~ according to claim 9 ~~one of claims 9 to 14~~, wherein said pharmaceutical composition is for topical application.

17. (currently amended) The method ~~Use~~ according claim 15, wherein an oral dosage unit of said pharmaceutical composition contains from 1 to 300 mg, preferably 1 to 150 mg, more preferably from 1 to 100 mg, and particularly from 1 to 50 mg of the agent(s).

18. (currently amended) The method ~~Use~~ according to claim 9 ~~one of claims 9 to 17~~, wherein ~~the pharmaceutical composition is for the treatment and/or prophylaxis of an individual having a HCV infection and/or a disease associated with HCV infection, whereby~~ the individual is a non-responder to interferon and/or ribavirin therapy.

19. (currently amended) ~~A~~ The composition of claim 1, wherein said composition is in unit dosage form for oral administration, ~~comprising as an active ingredient at least one agent selected from the group consisting of selenium, selenium salts, Vitamin D_3, all trans retinoic acid, C_1-C_{10} alkyl esters of all trans retinoic acid, salts of C_1-C_{10} alkyl esters of all trans retinoic acid, C_1-C_{10} alkyl amides of all trans retinoic acid, salts of C_1-C_{10} alkyl amides of all trans retinoic acid, 9 cis retinoic acid, salts of 9 cis retinoic acid, C_1-C_{10} alkyl esters of 9 cis retinoic acid, salts of C_1-C_{10} alkyl esters of 9 cis retinoic acid, C_1-C_{10} alkyl amides of 9 cis retinoic acid, salts of C_1-C_{10} alkyl amides of 9 cis retinoic acid, (E) 4 [2 (5,6,7,8 tetrahydro 5,5,8,8 tetramethyl 2 naphthalenyl 1 propenyl] benzoic acid (TTNPB), (4 [5,6,7,8 tetrahydro 5,5,8,8 tetramethyl 2 naphtalenyl) carboxamido] benzoic acid (AM 580), N (4 hydroxyphenyl) retinamide (4 HPR) and 6 [3 (1 adamantyl) 4 hydroxyphenyl] 2 naphthalene carboxylic acid (AHPN), and~~ further comprising a pharmaceutically acceptable carrier suitable for oral administration, said agent(s) being present in said unit dosage form in an amount of from about 1 to 50 mg wherein said unit dosage form is a tablet or capsule.

20. (original) The composition of claim 19, further comprising paraquat.

21-22. (canceled)

23. (currently amended) A method for regulating the production of Hepatitis C virus in cells or cell cultures and/or for preventing and/or treating Hepatitis C virus infection and/or diseases associated with HCV infection in cells or cell cultures, the method comprising ~~the step of~~ administering a pharmaceutically effective amount of an agent selected from selenium, selenium salts, Vitamin D_3, all ~~tans~~ trans retinoic acid, C_1 - C_{10} alkyl esters of all trans retinoic acid, salts of C_1 - C_{10} alkyl esters of all trans retinoic acid, C_1 - C_{10} alkyl amides of all trans retinoic acid, salts of C_1 - C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C_1 - C_{10} alkyl esters of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl esters of 9-cis retinoic acid, C_1 - C_{10} alkyl amides of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-~~naphtalenyl~~ naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN) to the ~~individual~~ cells or cell culture.

24-26. (canceled)

27. (currently amended) The method according to ~~one of~~ claims ~~21 to 26~~ 23 or 55, further comprising administering paraquat.

28. (currently amended) The method of claim 9, wherein said composition is in a unit dosage form~~Use of at least one of the agents selenium, selenium salts, Vitamin D_3, all trans retinoic acid, C_1 – C_{10} alkyl esters of all trans retinoic acid, salts of C_1 – C_{10} alkyl esters of all trans retinoic acid, C_1 – C_{10} alkyl amides of all trans retinoic acid, salts of C_1 – C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, salts of 9-cis retinoic acid, C_1 – C_{10} alkyl esters of 9-cis retinoic acid, salts of C_1 – C_{10} alkyl esters of 9-cis retinoic acid, C_1 –~~

~~C_{10} alkyl amides of 9-cis retinoic acid, salts of C_1 – C_{10} alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphtalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN) for the preparation of a unit dosage form of a pharmaceutical composition for the treatment and/or prophylaxis of a hepatitis C virus infection and/or a disease associated with HCV infection~~, the pharmaceutical composition further comprising a pharmaceutically acceptable carrier.

29. (currently amended) ~~Use~~ The method according to claim 28, wherein the composition further comprises at least one of the compounds all trans retinoic acid, pegylated α-, β-, and/or γ-interferon, non-pegylated (standard) α-, β-, and/or γ-interferon, and ribavirin.

30. (currently amended) The method ~~Use~~ according to claim 28 ~~or 29~~, wherein the selenium salt is sodium selenite.

31. (currently amended) The method ~~Use~~ according to ~~one of claims 28 to 30~~claim 28, wherein the composition further comprises paraquat.

32. (currently amended) The method ~~Use~~ according to claim 28 ~~one of claims 28 to 31~~, wherein said composition is for oral application.

33. (currently amended) The method ~~Use~~ according to claim 32, wherein the unit dosage form for oral application is a tablet or capsule.

34. (currently amended) The method ~~Use~~ according to claim 33, wherein the tablet or capsule comprises between 1 and 300 mg, preferably between 1 to 150 mg, more preferably between 1 to 100 mg, and particularly between 1 and 50 mg of the agent.

35. (currently amended) The method according to ~~one of claims 28 to 31~~claim 28, wherein said composition is for topical application.

36-41. (canceled)

42. (currently amended) A method for regulating the expression of the human cellular protein glutathione peroxidase-gastrointestinal in an individual comprising ~~the step of~~ administering to the individual a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D_3, all trans retinoic acid, C_1 - C_{10} alkyl esters of all trans retinoic acid, salts of C_1 - C_{10} alkyl esters of all trans retinoic acid, C_1 - C_{10} alkyl amides of all trans retinoic acid, salts of C_1 - C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C_1 - C_{10} alkyl esters of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl esters of 9-cis retinoic acid, C_1 - C_{10} alkyl amides of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-~~naphtalenyl~~ naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent inhibits or activates at least partially the transcription of DNA and/or the translation of RNA encoding said human cellular protein glutathione peroxidase-gastrointestinal.

43. (original) The method according to claim 42, wherein the individual is a non-responder to interferon and/or ribavirin therapy.

44-45. (canceled)

46. (currently amended) A method for regulating the expression of the human cellular protein glutathione peroxidase-gastrointestinal in cells or cell culture comprising ~~the step of~~ administering to the cells or cell culture a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D_3, all trans retinoic acid, C_1 - C_{10} alkyl esters of all trans retinoic acid, salts of C_1 - C_{10} alkyl esters of all trans retinoic acid, C_1 - C_{10} alkyl amides of all trans retinoic acid, salts of C_1 - C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C_1 - C_{10} alkyl amide of 9-cis retinoic acid, salts

of C_1 - C_{10} alkyl amide of 9-cis retinoic acid, C_1 - C_{10} alkyl esters of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl esters of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-~~naphtalenyl~~ naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent activates at least partially the transcription of DNA and/or the translation of RNA encoding said human cellular protein glutathione peroxidase-gastrointestinal.

47. (currently amended) A method for regulating the activity of the human cellular protein glutathione peroxidase-gastrointestinal in an individual comprising ~~the step of~~ administering to the individual a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D_3, all trans retinoic acid, C_1 - C_{10} alkyl esters of all trans retinoic acid, salts of C_1 - C_{10} alkyl esters of all trans retinoic acid, C_1 - C_{10} alkyl amides of all trans retinoic acid, salts of C_1 - C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C_1 - C_{10} alkyl amide of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl amide of 9-cis retinoic acid, C_1 - C_{10} alkyl amide of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl amide of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-~~naphtalenyl~~ naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent interacts with said human cellular protein glutathione peroxidase-gastrointestinal.

48. (original) The method according to claim 47, wherein the individual is a non-responder to interferon and/or ribavirin therapy.

49. (currently amended) A method for regulating the activity of the human cellular protein glutathione peroxidase-gastrointestinal in cells or cell culture comprising ~~the step of~~ administering to the cells or cell culture a pharmaceutically effective amount of an agent selected from ~~the group consisting of~~ selenium, selenium salts, Vitamin D_3, all trans retinoic

acid, C_1 - C_{10} alkyl esters of all trans retinoic acid, salts of C_1 - C_{10} alkyl esters of all trans retinoic acid, C_1 - C_{10} alkyl amides of all trans retinoic acid, salts of C_1 - C_{10} alkyl amides of all trans retinoic acid, 9-cis retinoic acid, C_1 - C_{10} alkyl esters of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl esters of 9-cis retinoic acid, C_1 - C_{10} alkyl amides of 9-cis retinoic acid, salts of C_1 - C_{10} alkyl amides of 9-cis retinoic acid, (E)-4-[2-(5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl-1-propenyl] benzoic acid (TTNPB), (4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-~~naphtalenyl~~ naphthalenyl) carboxamido] benzoic acid (AM-580), N-(4-hydroxyphenyl) retinamide (4-HPR), and 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthalene carboxylic acid (AHPN), wherein said agent interacts with said human cellular protein glutathione peroxidase-gastrointestinal.

50. (currently amended) The method according to any one of claims ~~36 to 49~~ 42, 46, 47, and 49, further comprising administering paraquat.

51. (new) The composition according to claim 5, wherein the individual afflicted with a HCV infection and/or at least one disease associated with HCV infection is a non-responder to interferon and/or ribavirin therapy.

52. (new) The method according to claim 15, wherein the individual is a non-responder to interferon and/or ribavirin therapy.

~~52~~ 53. (new) The method according to claim 9, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal or which activates or stimulates at least partially the production of said human cellular protein glutathione peroxidate-gastrointestinal.

~~53~~ 54. (new) The method according to claim 13, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal or which activates or stimulates at least partially the production of said human cellular protein glutathione peroxidase-gastrointestinal.

~~54~~ 55. (new) The method according to claim 18, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal or which activates or stimulates at least partially the production of said human cellular protein glutathione peroxidase-gastrointestinal.

~~55~~ 56. (new) The method according to claim 23, wherein said agent activates at least partially the activity of the human cellular protein glutathione peroxidase-gastrointestinal.